
Hyperbaric oxygen therapy: caveat doctor!

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Abstract

In the right hands, hyperbaric oxygen therapy is a safe and legitimately employed treatment modality for some specific medical conditions. It is not a panacea. It is a prescriptive treatment which should be administered only under the direct supervision of a trained hyperbaric physician. Caveat doctor!

Hyperbaric oxygen therapy (HBOT) is a treatment modality employed to treat a number of conditions which have been scientifically shown to have substantial benefit. At this time, there are only thirteen conditions that have been sanctioned by the Hyperbaric Oxygen Committee of the Undersea and Hyperbaric Medical Society (UHMS) and approved by the Federal Drug Administration (FDA) because ample evidence exists to support the use of HBOT, and not surprisingly, accepted for reimbursement by most third party insurers including Medicare and Medicaid. These conditions are: decompression sickness, arterial gas embolism, carbon monoxide intoxication, clostridial myositis and myonecrosis, acute traumatic ischemias, exceptional blood loss anemia, enhancement of wound healing in selected problem wounds, necrotizing soft tissue infections, delayed radiation injury, compromised skin grafts and flaps, thermal burns, refractory osteomyelitis, and intracranial abscess¹.

Though many other conditions have been treated using HBOT, there is no compelling, scientifically demonstrated evidence to support the usage of HBOT in those conditions. Enthusiastic patient testimonials, spotty case reports, equivocal controlled trials, and improved diagnostic tests without clinical correlation or improvement do not constitute adequate scientific evidence. Many of these conditions are of a desperate nature, cerebral palsy, stroke, multiple sclerosis, autoimmune diseases, to name a few, where patients and families are in search of a panacea. For some of these conditions, well designed studies have actually shown there to be no benefit with the use of HBOT. These conditions are often referred to as "off-label" or experimental and for which there is no third party reimbursement. While the FDA does not preclude the use of HBOT for these "off-label" conditions, it does require that they be so represented to the patient, that there be no assertion of clear benefit or cure to be de-

rived, and that there be no marketing or advertisement for these "off-label" uses². Furthermore, the patient is likely to be financially responsible for the costs of treatment. If they are being treated experimentally, then an appropriate study protocol should have been approved by an Institutional Review Board, appropriate informed consents obtained, and no cost should be borne by the patient.

The Undersea and Hyperbaric Medical Society has worked diligently since its inception in 1967 to "legitimize" the field of hyperbaric medicine within the conventional medical community. Indeed, the establishment of the Hyperbaric Oxygen Committee was undertaken and given the responsibility to continuously review research and clinical findings and to make recommendations regarding efficacy and safety of HBOT based upon sound physiological rationale, in vivo and in vitro studies demonstrating effectiveness, controlled animal studies, prospective clinical studies, and extensive clinical experience from recognized hyperbaric medicine centers. As a result, the committee reduced the number of indications from 28 to 13. Most third party insurers embrace the recommendations of this committee when deciding which conditions to reimburse.

As the body of knowledge and the need for "specialized" experts increased, the Society worked with the American Board of Medical Specialties to establish the sub-specialty board examination in Undersea and Hyperbaric Medicine sponsored by both the American Board of Preventive Medicine and the American Board of Emergency Medicine in 1999. To be eligible, candidates must have been trained in and have extensive clinical experience in, or have completed a 1 year fellowship in Undersea and Hyperbaric Medicine. As of 2005, only fellowship trained physicians will be allowed to sit for examination. Another major effort to enhance the nature and quality of hyperbaric facilities was the establishment of the UHMS Hyperbaric Facility Accreditation Program. This is equivalent to the Joint Commission for Accreditation of Hospitals and Organizations (JCAHO) for hyperbaric facilities. With the proliferation of hundreds of hyperbaric facilities throughout the United States during the past decade, the UHMS foresaw the need to create a

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mechanism to insure that hyperbaric facilities met minimum quality standards including adherence to established treatment conditions and guidelines.

HBOT administered for the approved conditions is not an "alternative" or "new age" medical application. Unfortunately, hyperbaric medicine has in the past, and continues to have in the present, a number of HBOT zealots and fanatics who trade upon less scrupulous practices with little regard for science which tarnish those of us who have labored so hard to engage this field in a professional manner, vis-à-vis a business enterprise aimed at promoting HBOT as a miracle cure for all manner of ills, the modern day "snake oil". Armed with minimal knowledge and training and enough capital to invest in procurement of a chamber, hyperbaric facilities are springing up in strip malls and shopping centers, in garages and private domiciles, even making house-calls with trailer mounted chambers, zip-up bags that pressurize on air to 5-6 feet of seawater pressure, all catering to a naïve, uninformed, and sometimes vulnerable population who trust someone adorned with a white lab coat offering them hope of a cure or amelioration for a price. And, what's more astounding is that many in these hyperbaric "boutiques" have little to no medical credentials to do so. For example, some commercial dive operators who may possess recompression chambers to treat diving accidents at a work site, now feel they can sell chamber time for other conditions, or entrepreneurs who prey directly upon the public with false or misleading advertising, or are at the very edge of truth. Many have their hearts in the right place, but are not neurologically intact. Others are out to make a quick buck. I should remind the reader that this is the practice of medicine, which is, by law, solely the purview of a licensed physician, preferably one trained and specialized in this field.

HBOT is the prescriptive administration of oxygen under increased atmospheric pressures, thus it must be "ordered" by a licensed physician who assumes the responsibility for its intended purpose as well as its unintended consequences or any untoward events arising from its administration. Many insurers including Medicare require a physician to be in attendance throughout the treatment in order to get reimbursed. Why? Because not unlike any other medical intervention, things don't always go as planned, and a chamber technician is not qualified to deal with medical emergencies should they arise.

So how can this happen? Beware of the patient that comes to you with a pre-printed prescription form for your signature. Chances are that there is no physician in attendance at the chamber, or there is only a nominally appointed one which would make you ultimately responsible for what happens to the patient while in that chamber. To avoid this pitfall, consult with the hyperbaric physician at the facility, ask about his/her training and credentials, ask about the treatment proto-

cols employed and how they are conducted before you refer your patient. You should not have to write the prescription or write an order for anything other than a consult. The hyperbaric physician in attendance will evaluate your patient and develop a treatment plan if appropriate, seek your concurrence, and write the prescription.

For the most part, the majority of hospital or university based hyperbaric facilities as well as some free-standing clinics do engage in the legitimate practice of hyperbaric medicine, meet or exceed quality standards of care, have qualified physicians in attendance, who treat only approved conditions or are engaged in active research protocols, whose facilities are or soon will be accredited by JCAHO or the UHMS. But beware of those infringing upon the legitimate practice of hyperbaric medicine, those who may not fully disclose to you your risk or liability, those who may adversely affect the safety and best interests mentally, physically, and financially of your patients.

References

1. Feldmeier John J. Hyperbaric oxygen 2003, indications and results. Kensington, MD, Undersea and Hyperbaric Medical Society, 2003
2. 21 Code of Federal Regulations 312. Federal Drug Administration, Washington, D.C., 2004

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